

# **SPL ER/DL Team**

## **January 4, 2012**

### **Minutes**

**Chair: Pat Cowall**

#### **1. Update from last mtg – Dec 7, Q&A with DRLS (Paul Loebach)**

- Draft minutes were sent out with the agenda
- Key topics (see more detail below):
  - Q2: new validation rule that requires link between establishment and product NDC
  - Q4: CMS is sending notification to drug list inner packs that have NDC numbers on them
  - Q5: Duplicate SPL on Daily Med – Lonnie will soon be sending out instructions on how to delete the duplicate SPL file.
- In the next few weeks, the SPL ER/DL team leads will be collecting questions, get responses, and publish them for everyone.

#### **2. Question 2 - new validation procedure will be implemented on Feb 1, 2012 that will require NDC codes to be included for each establishment.**

- This validation rule / requirement is not new. The rule has been in SPL implementation guide since 2010. Lonnie told tech team/vendors that this was coming last February, then again in September. He sent out an email in October to the SPL team leads, including me, with example of an SPL that has been posted to Daily Med. This is actually what prompted us to have the Q&A with Paul Loebach in December – in which we added this to our list of questions. In hindsight, we should have asked more questions in October.
- Sponsors should check with their SPL software vendors to make sure that they have this functionality in the tool
- Enter NDCs to the product level – not to the pack size level. The stylesheet does NOT allow 10 digit NDCs (ie to the pack level).
- Note: one vendor did notice a problem with adding NDCs for inner components of kits. Lonnie confirmed that the problem will be fixed by Feb 1.
- Question: does this apply only to final product SPL (eg private label distributors), or does this also apply to manufacturer SPL?
  - Pat responded that this applies to all SPL. The goal of this rule is to establish a clear supply chain for each product.
- In manufacturer SPL (ie manufactured for PLD), which NDC code is entered for the establishment – the NDC of the manufacturer (that uses the labeler code of the manufacturer) or the NDC of the final product (that uses the labeler code of the marketing company)
  - The product NDCs should be those that are included in the DPL section within the same SPL file. In a manufactured for PLD SPL – that uses the labeler code of the manufacturer – the product NDC code would also be that included in the DPL of that SPL – ie that uses the manufacturer's labeler code.

Discussion/questions to confirm with FDA/DRLS:

1. Is there any "talk" about eventually taking this down to the pack level? We would prefer to know sooner rather than later -- ie we don't want to go to all the work of collecting the data and putting product NDCs in the SPL now, and then have to re-do this down to the pack level next year.
2. We understand that DRLS is recommending that establishments/labelers provide complete supply chain information for each establishment. The focus of discussion/questions in the past have been related to manufacturing sites. Please confirm which establishments/business

operations will be REQUIRED to be linked to at least one product NDC code. ie are product NDCs required for:

- a. API sites – potentially all product NDCs in the SPL would need to be listed.
  - b. Analysis
  - c. Pack/label -- in many situations, the differences are seen at the pack level, and only product level NDCs can be entered. Thus you would enter the same NDC code for 2 different pack/label establishments.
  - d. etc.
3. This validation rule has been in the IG for a long time, but has not been implemented. There are many other rules in the IG that have not yet been implemented.
- a. Are any plans to implement any other validation rules that pharma should be aware of that are planned to be implemented in the near future?
  - b. We (ie pharma manufacturers/labels) would appreciate having specific notification of when new rules will be implemented – with enough notice such that we can communicate with our vendors to assure that the new release can be implemented effectively.

### **3 Question 4 - CMS request to drug list inner packs.**

- See minutes for complete discussion.
- Several sponsors noted that they received email communications from CMS last summer – we don't think this communication came by official letter. Also, no one on the call has received any communications within the last several months.
- Question: What will happen if they are not listed separately?
  - At risk that Medicaid will not reimburse the inner pack
- BMS has already drug listed the inner packs. FDA told them that it is ok to drug list the inner packs separately for reimbursement purposes -- even if they do not sell them individually.

### **4. Question 5 – process for deleting duplicate SPL files:**

- Lonnie is developing a process – you will include a reference to the duplicate SPL in the correct SPL file that you want to remain posted on Daily Med.
- The process is being reviewed by the SPL Tech Team and will be published after this review – within the next few months.
- Instead of asking for help deleting the duplicate files, please wait for the new process to be announced.

### **4. Walk-in items:**

- The section name for SPL Listing Data Elements is changing to Drug Product Listing. SPL can use either name between now and July 2012. After July 1, only the DPL section title will be allowed.
- DUNS portal: Jean confirmed with D&B that they are still working on the portal but have been delayed. They will get back to us next week with new timing.
- Howard said that one of his clients had received a request from FDA that they enter the vial components of a kit in the SPL. Howard wanted to know if anyone else had received this request. Pat responded that she had a similar request come in and pushed back with success.
  - However, the goal of the new validation rule is to have manufacturing supply chain information in the SPL. The component vials may be manufactured at different establishments – thus it would be good to be able to provide this level of detail in the SPL.
- SPL Request to include carton image in SPL instead of container. Has anyone else had this happen?
  - Carton typically has more information and preference for carton images has been stated in SPL training sessions
  - If carton is too big and isn't legible, Lonnie has told us to break it into 2 images.

- During the discussion, the subject came up that CMS sends out list of NDC codes and asks pharma to confirm that they are eligible / valid for reimbursement. This happens annually.
  - Pat confirmed that she reviewed the list of 2010 NDC codes at the end of November 2011.

### **3. Next meeting – January 18, 2012**

- Send us any other questions from the Q&A with DRLS.
- We will network responses with Paul Loebach and Lonnie and will send out responses to everyone.